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| APPLICATION NO.                            | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|--|----------------|----------------------|-------------------------|------------------|--|
| 09/972,016                                 | 10/04/2001     | Tariq M. Rana        | 267/302                 | 2378             |  |
| 23869 7:                                   | 590 06/09/2004 |                      | EXAMINER                |                  |  |
| HOFFMANN & BARON, LLP                      |                |                      | LUKTON, DAVID           |                  |  |
| 6900 JERICHO TURNPIKE<br>SYOSSET, NY 11791 |                |                      | ART UNIT                | PAPER NUMBER     |  |
| 51035E1, N                                 | 11771          |                      | 1653                    |                  |  |
|  |                |                      | DATE MAILED: 06/09/2004 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |   | Application    | No.  | Applicant(s)                  |  |  |  |
|---|---|----------------|--|-------------------------------|--|--|--|
| Office Action Summary   |   | 09/972,016     |  | RANA ET AL.                   |  |  |  |
|   |   | Examiner       |  | Art Unit                      |  |  |  |
|   | •   | David Lukto    | on   | 1653                          |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address   |   |                |  |                               |  |  |  |
| Period for Reply  |   |                |  |                               |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                |  |                               |  |  |  |
| Status  |   |                |  |                               |  |  |  |
| 1) Responsive to communication(s) filed on 24 May 2004.   |   |                |  |                               |  |  |  |
| 2a) This action is <b>FINAL</b> . 2b) This action is non-final.   |   |                |  |                               |  |  |  |
| 3) Since this app   | lication is in condition for allow  | vance except f | or formal matters, pr  | osecution as to the merits is |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  |   |                |  |                               |  |  |  |
|   |   |                |  |                               |  |  |  |
| Disposition of Claims  4)  Claim(s) 1-27 is/are pending in the application.  4a) Of the above claim(s) 1-14 and 19-27 is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) 15-18 is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) are subject to restriction and/or election requirement.  Application Papers  9)  The specification is objected to by the Examiner.  10)  The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |                |  |                               |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |                |  |                               |  |  |  |
| Priority under 35 U.S.C. § 119  |   |                |  |                               |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |                |  |                               |  |  |  |
| Attachment(s)  1) Notice of References 2) Notice of Draftspersor 3) Information Disclosure Paper No(s)/Mail Date  | n's Patent Drawing Review (PTO-948)<br>e Statement(s) (PTO-1449 or PTO/SB | )<br>3/08)     | 4) Interview Summa Paper No(s)/Mail 5) Notice of Informa 6) Other: |                               |  |  |  |

Applicants' election of the following species is acknowledged:

(a) for the "modified protein", the following peptide has been elected, wherein "X" represents a modified tyrosine:

## X-G-R-K-K-R-R-Q-R-R

- (b) rhodamine as the acceptor dye, and
- (c) fluorescein as the donor dye.

Claims 1-14 and 19-27 are withdrawn from consideration.

 $\diamondsuit$ 

Claims 15-18 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 15 recites (lines 1-2) the term "physiological conditions". The meaning of this is unclear, since the assay is conducted *in vitro*.
- Claim 15 recites (last line) the phrase "determining the interaction". The
  meaning of this is unclear. The term "interaction" could refer to any of a
  number of chemical or physical phenomena. Is the "interaction" one of
  attraction or repulsion? Does the phrase at issue refer to a distance measurement
  of some kind? How does one draw an inference as to the nature of the
  interaction?

• Claim 17 makes reference to "acetyl-tyr-tat" peptide. What is the structure of this compound?

 $\diamondsuit$ 

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 15, 16 and 18 are rejected under 35 U.S.C. §103 as being unpatentable over Karn (USP 6,573,045).

Karn discloses methods of assessing RNA/peptide interactions by FRET. Various donor/acceptor pairs are listed in table 2 (col 40). In various experiments, RNA was labeled with DABCYL, and the peptide was labeled with rhodamine. (see, e.g., col 35, line 60+; col 37, line 20+; col 37, line 50+). In this particular configuration, rhodamine is the donor, and DABCYL is the acceptor. The rhodamine/fluorescein pair is also disclosed (e.g., table 2, col 40).

Thus, the claims are rendered obvious.

 $\Leftrightarrow$ 

Claims 15 and 16 are rejected under 35 U.S.C. §103 as being unpatentable over Karn (USP 6,416,194).

Karn discloses methods of assessing the interaction between antimicrobial compounds and RNA using FRET. Among the antimicrobial compounds are various peptides and proteins. Also disclosed (table 6, col 28) are various donor/acceptor pairs for FRET. Also disclosed (col 13, line 55+) that the donor can be attached to the RNA, and the acceptor to the antimicrobial, or vice versa; i.e., the implication is that either approach will provide useful information. The fluorescence spectroscopist of ordinary skill would have been motivated to use one of the donor/acceptor pairs listed to study interactions between antimicrobial peptides, and RNA.

Thus, the claims are rendered obvious.

Claims 15, 16 and 18 are rejected under 35 U.S.C. §103 as being unpatentable over Zhang (*J. Biol. Chem.* 275, 34314, 2000).

Zhang discloses a study of the interactions between TAR RNA and a tat peptide, using FRET. Fluorescein was bonded to the RNA, and rhodamine to the peptide, which is the opposite of that specified in the instant claims. However, the fluorescence spectroscopist of ordinary skill would regard the rhodamine-RNA/ fluorescein-peptide pair as providing the same information as the fluorescein -RNA/ rhodamine -peptide pair, i.e., that fluorescein -RNA/ rhodamine -peptide pair would provide no advantage over the other.

Thus, the claims are rendered obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Dikokyan

